

BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM
FOR HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Abstract of the Disclosure

5 A biphasic controlled release delivery system for
pharmaceuticals which have high water solubility, such as
the antidiabetic metformin HCl salt, is provided which
provides a dosage form that has prolonged gastric
residence so that a dosing regimen of at least one gram
10 metformin, once daily, may be achieved while providing
effective control of plasma glucose. The delivery system
includes (1) an inner solid particulate phase formed of
substantially uniform granules containing a
pharmaceutical having a high water solubility, and one or
15 more hydrophilic polymers, one or more hydrophobic
polymers and/or one or more hydrophobic materials such as
one or more waxes, fatty alcohols and/or fatty acid
esters, and (2) an outer solid continuous phase in which
the above granules of inner solid particulate phase are
20 embedded and dispersed throughout, the outer solid
continuous phase including one or more ^{hydrophilic}~~hydrophobic~~
polymers, one or more hydrophobic polymers and/or one or
more hydrophobic materials such as one or more waxes,
fatty alcohols and/or fatty acid esters, which may be
25 compressed into tablets or filled into capsules. Methods
for forming the so-described biphasic controlled release
delivery system and using such biphasic controlled
release delivery system for treating diabetes are also
provided.

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